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EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,608	EBLE ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3*

10577608 - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *7-10,14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 11-13* is/are rejected.

7)☐ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/7/2006, 9/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 11-13, drawn to a process for preparing amorphous active substance formulations comprising steps a) – e).

Group II, claim(s) 7-9 and 14-15, drawn to a predominantly amorphous active substance formulation comprising an active substance A), a polymer B), and a dispersing agent C).

Group III, claim(s) 10, drawn to crop protection agents in the form of active substance-containing suspensions in water or aqueous solvents and pharmaceutical preparations in oral dosage form.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Compositions comprising an active substance, a polymer and dispersing agents and processed for their preparation are known in the art as evidenced by the following patents: US 5,780,062, EP 1,344,520, and US 6,458,745. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

During a telephone conversation with William Gerstenzang on April 8, 2010 a provisional election was made with traverse to prosecute the invention of Group I, claim 1-6 and 11-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-10 and 14-15 will be withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner during the telephone conversation requested an election of species for the solvent in claim 12. The examiner is withdrawing that request. There will be no election of species requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is reminded in order for the restriction requirement to be complete an election of a single invention from Groups I-III should be made.

Claims 1-15 are pending in the Application. Claims 7-10 and 14-15 will be withdrawn from further consideration, as being drawn to a non-elected invention. Claims 1-6 and 11-13 will presently be examined to the extent they read on the elected subject matter of record.

Priority

The application is a national stage entry for PCT/EP04/11807 filed October 19, 2004, which claims priority to foreign German Application No. 103 51 087.7 filed October 31, 2003.

Information Disclosure Statement

Receipt of Information Disclosure Statements filed September 7, 2006 and September 20, 2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a process for preparing amorphous active substance formulations comprising the steps of a) dissolving an active substance A) in a solvent 1, optionally together with a dispersing aid C) to form a solution E); b) providing a liquid displacement agent 2, in which the solubility of the active substance A) is less than 1% by weight and which is miscible in solvent 1 and which effects precipitation of the active substance A, as solution F; c) adding a predominantly amorphous polymer B) which is readily soluble in water to the solution from step a) and/or to solution F) from step b; d) mixing solvent streams of solutions E) and F), optionally in a mixing nozzle, with the two streams being fed continuously and uniformly to the mixing zone of the mixing nozzle, optionally forming a turbulent flow in the mixing zone; and e) removing the solvents from the mixture by freeze drying, spray drying or spray granulation. In view of University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886, (U.S. Court of Appeals Federal Circuit, 2004), the claims do not identify any compound(s) or provide evidence that that those skilled in the art could identify active substances, solvents, and displacement agents to be used in the process based on the claims' vague functional description. At best, it simply indicates that one should run tests on a wide spectrum of active substances, solvents, and displacement agents in the hope that at least one of the many possible combinations of the active substances, solvents, and displacement agents will provide the desired functional limitations, solubility of active substance A, miscibility with solvent 1 and precipitation

effects. The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art,* (2) *partial structure,* (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification discusses on pages 6-8, a myriad number of possible active substances that can be used in the active substance A, including crop protection agents and pharmaceutical agents. The specification also discusses a number of possible organic solvents that can be used as solvent 1 and that the displacement agent can be water or an aqueous solution of an acid, of a base or a salt. The specification further discusses a provision for a displacement agent 2, a liquid 2, in which the solubility of the active substance A is less than 1% by weight and which is miscible with solvent 1 and which effects precipitation of the active substance A) (page 2, lines 14-16).

The claims are drawn to a process for preparing amorphous active substance formulations comprising the steps of a) – e).

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed. A review of the language of the claims indicates that these claims are drawn to any active agent, any solvent 1, and any

displacement agent , in which the solubility of the active substance A is less than 1% by weight and which is miscible with solvent 1 and which effects precipitation of the active substance A). The specification discloses specific species in preparation examples 1-6 on pages 13--18.

The disclosure of the disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claims encompass any and all active substances, solvents, and displacement agents, particularly displacement agents in which the solubility of the active substance A is less than 1% by weight and which is miscible with solvent 1 and which effects precipitation of the active substance A. There is substantial variability among the species of active substances, solvents and displacement agents encompassed within the scope of the claims because the specific species in examples 1-6 are only representative molecules amongst an entire class of molecules that can have widely differing structures and corresponding biological activities. Further, defining the composition in functional terms would not suffice in the absence of a disclosure of structural features or elements of the active substances, solvents, and displacement agents that would have the stated function. Applicant is describing what the displacement agent does rather than what it is. Describing a compound by its functions will not substitute for written description of the structure of the compound. The invention should be explained in such a way as to describe what the invention is, not what the invention does. Describing the function of a compound fails to distinguish the compound from other molecules or agents that can perform the same functions.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Consequently, the Examiner notes that the claimed invention which is drawn to a genus of active substances, solvents, and displacement agents may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Here, the specification does not disclose the common structural feature shared by the members of the claimed genus. Since the claimed genus encompasses active substances, solvents, and displacement agents yet to be discovered, the disclosed undisclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of active substances, solvents, and displacement agents does not provide an adequate description of the claimed genus.

Weighing all the factors, the breadth of the claims reading on active substances, solvents and displacement agents yet to be discovered, the lack of correlation between structure and function of the active substances, solvents, and displacement agents, level of knowledge and skill in the art, one of ordinary skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of all active

substances, solvents, and displacement agents. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms that are common to the genus. That is, the specification provides neither a representative number of all active substances, solvents, and displacement agents to describe the claimed genus, nor does it provide a description of structural features that are common to the all active substances, solvents, and displacement agents. In essence, the specification simply directs those skilled in the art to go figure out for themselves the structure of the claimed active agents, solvents, and displacement agents.

The written description requirement is not satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant claims in claim 1, step c), line 1, of the process a "predominantly" amorphous polymer. The term "predominantly" is a relative term. It is unclear what Applicant is trying to convey, is the polymer amorphous or is it not amorphous? Applicant should clearly convey what is meant by the term "predominantly".

Applicant claims in claim 1, step c), line 2, "readily" soluble in water. The term "readily" is indefinite. "Readily" could have different definitions for persons of ordinary

skill in the art. What may be “readily” for one person who is of ordinary skill in the art, i.e. 3 seconds, may differ from another person who is of ordinary skill in the art, i.e. 3 minutes. Applicant should indicate what is meant by the term “readily”.

Claim 6 recites the limitation "the suspension" in line 3. There is insufficient antecedent basis for this limitation in the claim. The claim recites “the drying step e) is preceded by addition to “the suspension”, which means the suspension would have been formed in step d). Step d) recites the mixing of “solvent streams of solutions E) and F). There is no recitation of a “suspension” in step d).

Claim 6 includes the term "of" in line 3 after the term "suspension". It is unclear if "of" should be followed by additional terms describing the suspension or if "of" should be deleted. Appropriate correction is required.

The portion of step d) of mixing in a nozzle is an optional step and is therefore, not considered an essential element of the process for preparing amorphous active substance formulations. The examiner will examine the claims with the mixing in a nozzle as being optional.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Frank et al. (US 5,780,062).

Frank et al. disclose the formation of small particles of organic compounds by precipitating said organic compounds in an aqueous medium containing polymer/amphiphile complexes (Abstract). Frank et al. disclose 1) dissolving a pharmaceutically active compound, such as an antihyperlipidemic agent, in a first solvent which is water-miscible (step a); 2) dissolving polyvinylpyrrolidone and sodium dodecylsulfate in a second solvent which is aqueous such as water and in which the active compound is more or less insoluble (steps b and c). The concentrations of both polyvinylpyrrolidone and sodium dodecylsulfate are such that the system is below the critical concentration at which free micelles form and precipitation of the polymer/amphiphile complex has not occurred; 3) adding the solution obtained from step (1) to that prepared in step (2) while keeping the latter under constant agitation (step d). Precipitation occurs and results in a suspension of drug/polymer/amphiphile small particles. The small particles thus obtained are flocculated by the addition of an aqueous solution of an electrolyte, such as potassium phosphate. 5) The suspension is centrifuged and washed twice with water, centrifuged, redispersed in water and then freeze-dried (step e) (col. 4, lines 8-30). Frank et al. disclose the first solvent is a solvent or mixture of solvents in which the organic compound of interest is relatively soluble and which is miscible with the second solvent. Examples of such solvents include, but are not limited to: methanol, ethanol, isopropanol, acetone, dimethylformamide, and acetonitrile (col. 2, lines 66-67-col. 3, lines 1-4) (solvent 1,

organic solvent). Frank et al. disclose the second solvent is water or an aqueous solution containing one or more of various additives (col. 3, lines 5-7) (displacement agent, water). Frank et al. disclose a polymer, the solution of which is prepared in the second solvent, is meant to be a wide variety of organic chemical entities of relatively high molecular weight include polyvinylpyrrolidone and polyethylene glycols (col. 3, lines 23-31) (polymer B). Frank et al. disclose collection of the small particles can be achieved by various methods, such as, 1) freeze-drying, 2) spray-drying and 3) fluidized-bed drying (col. 3, lines 62-67-col. 4, lines 1-4).

Frank et al. meet all the limitations of the claims and thereby anticipate the claims.

Claims 1, 4-6, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Albayrak et al. (EP 1,344,520).

Albayrak et al. disclose a method for the preparation of nano-or microparticles comprising peptides, proteins, or other water soluble or non-water soluble bioactive substances and to particles provided according to the method (page 2, paragraph 1). Albayrak et al. disclose active substances are embedded or encapsulated in a polymer matrix by the steps of a) effecting precipitation of an active substance in a solution which comprises a polymer dissolved in an organic solvent to obtain a suspension of the active substance, b) mixing the obtained suspension with an aqueous surfactant solution and solidifying the polymer to obtain a suspension of nano-or microparticles which contain an active substance (page 2, paragraph 7). Albayrak et al. disclose a

convenient method for carrying out step a) starts from a solution of an active substance in water or an organic solvent which is mixed with the solution of the polymer in an organic solvent (steps a, b, and c) (page 2, paragraph 11). Albayrak et al. disclose the active substance is dissolved in a smaller amount of a first solvent L1. The polymer solution is prepared with the help of a larger amount of a second organic solvent L2 which dissolves the polymer, but is a non-solvent (anti-solvent) for the active substance. Then, L1 and L2 including the substances dissolved therein are combined. Upon combination of L1 and L2, precipitation of the active substance, which is insoluble in L2, is effected to yield a suspension of the active substance in the polymer solution. Albayrak et al. disclose the solvents L1 and L2 should be fully or partially miscible with each other for this purpose (page 3, paragraph 11). Albayrak et al. disclose solvents which may be used for the preparation of the polymer solution and for the preparation of a solution of the active substance prior to the precipitation step include alkyl acetates, alkyl formates, acetone, and ethanol (specific solvent 1 and displacement agents) (page 5, paragraph 35). Albayrak et al. disclose suitable surfactants to provide the aqueous surfactant solution in clued polyvinyl alcohol and polyvinyl pyrrolidone (page 6, paragraph 37). Albayrak et al. further disclose once the solidification of the polymer in step b) is completed, the organic solvent or solvent mixture can be removed via conventional methods such as application of a reduced pressure and/or a flow of air or nitrogen, filtration or extraction (page 5, paragraph 35). Albayrak et al. disclose in order to increase their stability, the drug loaded nano-or microparticles may be lyophilized

together with a cryoprotectant such as a sugar, sugar alcohol or polyvinyl pyrrolidone derivative (page 6, paragraph 41) (high molecular weight sugar).

Albayrak et al. meet all the limitations of the claims and thereby anticipate the claims.

Claims 1-2, 4-6, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Runge et al. (US 6,458,745).

Runge et al. disclose a solid crop protection composition consisting essentially of a) one or more amorphous crop protection active ingredients which are solid per se and have solubility in water of less than 500 mg/l at 25º C and b) a coating enclosing component (a) (Abstract).Runge et al. disclose to achieve particles as small as possible upon mixing, it is expedient to produce a vigorous turbulence in the mixing chamber by stirring or shaking the active the active ingredient solution and the dispersing solution with mechanical aids or, in particular, by injecting a forced stream of these two components into a mixing chamber (col. 9, lines 55-60). A suspension of the crop protection active ingredient in the solvent of choice in concentration of 0.1 to 50% by weight of stabilizers, is introduced into container (1). Container (2) contains the solvent without admixture of the crop protection active ingredient. The active ingredient suspensions and the solvent are fed to the mixing chamber via pumps. It being possible for the mixing ratio to be set by selecting the flow rate of each of the pumps and it is chosen in such a way that an active ingredient concentration of 0.02 to 40% by weight based on the solution is formed in the mixing chamber (col. 9, lines 63-67-col. 10, lines 1-11). Runge et al. disclose before entering the mixing chamber, the solvent is brought

to the desired temperature via the heat exchanger. Turbulent mixing causes the active ingredient to dissolve in the temperature range of 20º C to 240º C, and the resulting solution enters the second mixing chamber in which the active ingredient is precipitated in colloid-disperse form by admixing the dispersing solution via pump. The fine active ingredient dispersion leaves via the pressure control valve and enters the storage container (col. 10, lines 12-21). Runge et al. disclose the solvents can be removed from the colloid-disperse intermediate in a manner known per se, such as freeze drying. The preferred method is spray granulation, in particular spray drying and the twin emulsion method (col. 10, lines 38-46). Runge et al. disclose to promote the disintegration of agglomerates upon dispersing the dry powder prior to use, the addition before drying of a spray adjuvant such as lactose or polyvinlpyrrolid-2-one to the colloid-disperse product after the mixing step is advantageous (col. 10, lines 55-59). Runge et al. disclose in a preferred embodiment of the process, the active ingredient solution is prepared in the presence of a stabilizer. Very particularly preferred are ascorbyl palmitate and copolymers of acrylic acid and styrene (col. 10, lines 60-65). Runge et al. disclose the preparation of a dry powder in preparation example 1, col. 14, lines 65-67-col. 15, lines 1-41. Chlorpyrifos was stirred into a solution of ascorbyl palmitate in acetone giving a clear solution. This solution was mixed with acetone in the mixing chamber. The chlorpyrifos was precipitated in colloid-disperse form in such a way that, after a residence time of 3.2 seconds, the molecular disperse solution was fed into the mixing chamber (step a). There, the material was mixed with an aqueous solution of gelatin B 100 Bloom, Gelita Sol P and lactose in fully demineralized water (steps b, c,

and d). A white, cloudy colloid-disperse chlorpyrifos dispersion was obtained in the receiving vessel. Spray drying of the product from Preparation Example 1 a) gave a free-flowing nanoparticulate dry powder (e).

Runge et al. disclose suitable organic solvents which are miscible with water include alcohols, ethers, esters, ketones and acetals of this type. Substances include ethanol, isopropanol, and acetone (col. 9, lines 25-34) (solvents). Runge et al. disclose materials that are suitable for coating are boundary-or surface acting polymeric colloids or amphiphilic (col. 7, lines 40-43). Runge et al. disclose polymeric colloids include gelatin, dextrin, gum, alginates and starch (col. 7, lines 44-51). Runge et al. disclose suitable synthetic anionic, cationic, and neutral polymers include polyvinyl alcohol and polyvinylpyrrolidone (col. 7, line 52-62) (polymer B).

Runge et al. meet all the limitations of the claims and thereby anticipate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Albayrak et al. (EP 1,344,520).

Applicant's Invention

Applicant claims a process for preparing amorphous active substance formulations comprising steps a)-e). Applicant claims the viscosity of solutions E) and F) is kept below 100 mPas.

Determination of the scope of the content of the prior art
(MPEP 2141.01)

The teachings of Albayrak et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)

Albayrak et al. do not teach that the viscosity of solutions E) and F) is kept below 100 mPas.

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of Albayrak et al. and keep the viscosity of the use solutions E) and F) below 100 mPas as a matter of routine experimentation and optimization. One skilled in the art at the time the invention was made would have been

motivated to keep the viscosity below 100 mPas to optimize the rate of flow of the solutions when mixing the solutions streams, particularly if using equipment that has mixing nozzles to ensure the solutions will flow through the nozzles. The adjustment of particular conventional working conditions (e.g., determining viscosity) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDRIAE M. HOLT whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616